REMARKS

Claims 8-13 have been cancelled without prejudice or disclaimer and new claims 34-39 added.

The device which is the subject of the present invention is for use in apparatus for actively assisting in direct cardiac compression. The apparatus comprises in essence these components:

(a) an actuator (that is the device of the present invention),

(b) a control system based on ECG or pressure or operating without either trigger signal, and

(c) an energy source.

The important features of the heart actuator device of the present invention as defined by claim 1, which is used in an active heart assist apparatus, include:

(i) a paddle-like main body which includes a heart compressing wall which in use is affixed to at least a region of the heart; and

(ii) the main body includes a distal wall and the heart compressing wall is movable away from the distal wall so as to compress the region of the heart to which it is affixed.

These features provide for significant advantages. First, because the paddle-like main body is affixed to the heart, it does not interfere with size changes in the heart, and, further, because the heart is generally unconstrained, the problems with devices that encase the heart are avoided. These problems are described in some detail in the paragraphs bridging pages 6 and 7 of the specification.

Additional advantageous features of the device in its various preferred forms are defined in the dependent claims. For example, claims 2-4 define the main body as having two major walls, one of which defines the heart compressing wall and the other defining the distal wall, the heart compressing wall being curved inwardly and the distal wall being curved outwardly. Furthermore, the distal wall has a greater degree of stiffness than the heart compressing wall. This particular structure enables the heart compressing wall to conform to that part of the heart to which it is affixed regardless of any variation in the size of the heart. The relative rigidity of the

distal wall to the heart compressing wall ensures that a positive compression of the heart is effected by the heart compressing wall.

A further particularly advantageous feature of the device in a preferred embodiment of the present invention is the provision of the device of the present invention of biocompatible material for affixing the heart compressing wall to the heart.

Claims 1-7, 14, 15 and 25-33 are rejected as anticipated by Wardle. Claims 16-24 are rejected as obvious over Wardle in view of Smith and further in view of Heilman et al. These rejections are respectfully traversed.

The apparatus described in Wardle is entirely different to the device of the present invention. The Wardle apparatus is in essence a passive girdling device for supporting the heart.

The Wardle device includes a frame 12 which is sutured to the heart. In use, the heart is encased almost in its entirety within the frame 12. Attached to the frame 12 are a series of inflatable pockets 22 each of which has associated with it a highly elastic recoil balloon 24. The inflation pocket 22 is on the inside of the frame 12 and the recoil balloon 24 is on the outside of the frame 12. Each associated pocket 22 and balloon 24 are in fluid communication with one another via ports 20 in the frame 12. There are various embodiments described but, in essence, they are all of the same general construction to that described above.

The purpose of the pockets 22 is to support the wall of the heart ventricle. The pockets 22 are not attached to the heart wall. The operation of the device is described in the first paragraph of column 9. As described when the device is first placed on the heart, the pockets are completely collapsed. Fluid is then introduced into the space between the pocket and its associated balloon and the pocket is brought into contact with the heart. As is described, the pockets act as an external restraining force.

Basically, the Wardle device is specifically for contaminant of the heart. It surrounds or encases the heart so as to confine and control ventricular diastolic expansions. The inflation pockets are primarily provided to allow for adjustment of the constraint on the heart. Thus, the Wardle device suffers all of the disadvantages of the prior art devices which constrain the heart as discussed in the patent specification.

As described above, the Wardle device includes a more rigid inflation pocket made of high strength, low elasticity material in contact with the heart (col. 4, lines 40-48). The recoil balloon (24 in Fig. 1) on the non-heart contacting side is fabricated from a thin, high elasticity

material (col. 4, line 66 to col. 5, line 1). If active pressure is applied to the device as described in col. 11, lines 10-29, it would first and foremost inflate the device away from the heart instead of compressing the heart. This is entirely contrary to the device of the present invention.

Because the pockets are not attached to the heart, there would be a tendency to set up an irritation at the heart surface interface due to the continued mechanical contact and rubbing. This could cause damage to the surface coronary arteries and/or interface with coronary blood flow. Such irritation is likely to cause production of serious fluid which can be of substantial volume. Despite the provision of "port holes" (col. 4, lines 37-39), such an effusion can collect in pockets inside or around the "containment" device (pericardial effusion) and even result in serious disturbance in the heart's ability to fill or empty. There are comparable clinical disease states which can create medical emergencies (e.g., perdicardial tamponade).

The Wardle patent specification contemplates an arrangement that will provide some active assist during systole. Clearly, the pressure applied to the heart during systole would come from the recoil component of the inflatable pockets on the outside of the "containment frame or structure." The pressure build-up during diastole in the outer recoil balloons is, in the applicant's view, unlikely to be sufficient to lend any support during systole. The pressure in these external inflatable pockets would come from the force of heart dilation during diastole. If at this phase of the heart's cycle the pressure is more than 20 mmHg inside the heart, its diastolic function is compromised to a degree that the heart is "strangled" by the device. Also, the pressure throughout the circulation settles at around 20 to 30 mmHg when the heart stops (known as "Mean Circulatory Pressure"), making the Wardle device quite ineffective during this not infrequent occurrence in patients with severe heart failure, the group for which the device is intended.

In conclusion, the Wardle patent describes a complicated passive heart assist device which has many drawbacks. The Wardle patent aims to allow for adjustments in volume and pressure inside the containment frame and the inflation pockets to accommodate different sized hearts. There are strong *prima facie* grounds for concluding that the Wardle device is quite unsuited for use as an active device for the failing heart.

The secondary references are cited to show monitoring the mechanical and electrical activity of the heart. However, these references clearly do not show the important features of the present invention.

Claims 8-13 have been rewritten in independent form as claims 34-39, including all of the limitations of the base claim and any intervening claims. Thus, claims 34-39 are in condition for allowance.

In view of the foregoing, early and favorable action is respectfully requested.

A Petition For Extension Of Time is being filed concurrently herewith.

The Commissioner is hereby authorized to charge any fees due in connection with the present Amendment to Deposit Account 19-4293.

Respectfully submitted,

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